An Overview

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THE NATIONAL CHILDREN'S STUDY

Outline

- Why the NCS was proposed
- What the NCS proposes to accomplish
- How the NCS is being planned
- Status and progress with the NCS

Children's Increased Vulnerability

- Children have increased vulnerability to environmental exposures
- Critical windows of vulnerability during development
- Immature mechanisms for detoxification and protection
- Differences in metabolism and behavior that may yield higher exposure in the same environments
- Some children are more vulnerable than others

Risky Behavior

Current Known Exposure Levels

2nd National Report on Human Exposure to Environmental Chemicals*

AGENT	LEVEL	THRESHOLD	SAMPLE
Mercury - Blood	0.34ug/L mean	15ug/L	705, 1-5 yrs
Phthlate, mono-ethyl (urine)	91.3ug/L mean	?	328, 6-11 yrs
PCB's	Not measured <12 yrs.		
Phytoestrogen Enterolactone	315ug/g creat. (urine)	?	331, 6-11
Chlorpyrophos metabolite	3.1ug/g creat. (urine)	?	481, 6-11yrs
1 Napthol 90th %ile	4.5ug/g creat. (urine)	?	483, 6-11yrs

*http://www.cdc.gov/exposurereport/pdf/SecondNER.pdf

President's Task Force

- 1998 Task Force on Environmental Health and Safety Risks to Children
- Charge – Develop strategies to reduce risk of environmental exposures to children
- Co-chairs
  - Secretary HHS
  - Administrator USEPA
- Members
  - 7 more cabinet officers
  - Senior staff
- Many risks not clear or quantified

President's Task Force (cont.)

- Need for additional study of effects of environmental exposures (broadly defined)
- Consultation January 2000 endorsed Study: large, bold, multiple agencies, public private partnerships
- New money would be required

Rationale

- Converging factors
  - Increased vulnerability to environmental exposures in children in general
  - Exposures to some agents have caused serious developmental effects – lead, alcohol
  - Known current exposures of high frequency – pesticides, phthalates, violence, etc.
- Existing studies limited in size & scope
- Study needed to identify effects or assure safety
- Longitudinal design to infer causality with multiple exposures and multiple outcomes

PL 106-310: Children's Health Act of 2000

- (a) PURPOSE - … to authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

- (b) IN GENERAL - The Director of NICHD shall establish a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to:
  - (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
  - (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes…
  - (3) consider health disparities among children which may include the consideration of prenatal exposures.
- (e) AUTHORIZATION OF APPROPRIATIONS - There are authorized to be appropriated to carry out this section $18,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2002 through 2005.

Study Concepts

- Longitudinal study of children, their families and their environment
- National in scope
- Hypothesis driven
- Environment defined broadly (chemical, physical, behavioral, social, cultural)
- Study common range of “environmental” exposures and less common outcomes (n~100,000)

Study Concepts (cont.)

- Exposure period begins in pregnancy
- Environment & genetic expression
- State-of-the-art technology
  - Tracking
  - Measurement
  - Data management
- Consortium of multiple agencies
- Extensive public-private partnerships
- National resource for future studies

Potential NCS Impact on Selected Health Outcomes

Health Outcome	Estimated Annual Economic Burden (in billions of 2003$)	Range of Potential Reductions Attributable to NCS	Potential Annual Economic Savings from NCS
Asthma	$14.5	3 – 7 %	$0.4 – 1.0 billion
Obesity (excl. diabetes)	$46.3	2 – 4 %	$0.9 - 1.9 billion
Low Birth Weight	$13.1	4 – 7 %	$0.5 - 0.9 billion
Mental Retardation	$51.2	2 – 5 %	$1.0 - 2.6 billion
Injuries/Deaths from Aggressive Behavior			
Motor Vehicle Accidents	$19.0	3 – 7 %	$0.6 - 1.3 billion
Violence	$24.3	0.5 – 1.5 %	$0.12 – 0.37 billion
Impaired Cognitive Ability (1 IQ point) from:			
Mercury Exposure	$0.8 (60,000 at-risk newborns)	5 - 15 % (of at-risk newborns)	$0.04 - 0.12 billion
Nonpersistent Pesticide Exposure	$49.0 (90 percent of births)	0.3 – 0.7 %	$0.15 - 0.34 billion
Autism	$40.6	0.5 – 1.5 %	$0.2 - 0.6 billion
Total	**$268.8 billion**		**$3.8-8.6 billion**

The NCS Will Provide

- The answer to concerns about known exposures during childhood to potential toxicants
- The power to determine absence of effects or benefit of exposures to various products important for our economy
- Causal factors for a number of diseases and conditions of children with suspected environmental causes
- How multiple causes interact to result in multiple outcomes

The NCS Will Provide (cont.)

- Large sample size required to apply knowledge of the human genome to understand multi-factoral genetic conditions
- Identification of early life factors that contribute to many adult conditions
- A national resource to answer future questions by using stored biological and environmental samples and the extensive data for decades to come
- Information feedback to participants and communities for their use

Funding Status

- Start-Up
  - FY04 – FY05
  - $26 million estimated need for FY05
- Implementation
  - FY06 – FY30
  - Approx. $100 million per year